

NOTE: Please note minor schedule change on Wednesday. Dr. Beauchamp will present at 10:00am.
The Informed Consent & Decisionally impaired session will begin at 11:30am and run from 1:30 – 3:30pm. after lunch

DEPARTMENT OF HEALTH AND HUMAN SERVICES
MEETING OF THE
NATIONAL HUMAN RESEARCH PROTECTIONS ADVISORY COMMITTEE (NHRPAC)

TUESDAY, OCTOBER 30 & WEDNESDAY, OCTOBER 31, 2001

THE DOUBLETREE HOTEL
1750 ROCKVILLE PIKE
ROCKVILLE, MARYLAND 20852
301/468-1100

AGENDA

Tuesday, October 30, 2001

8:30am - 9:00am	WELCOME --OVERVIEW OF MEETING Mary Faith Marshall, Ph.D. Chairperson, NHRPAC
9:00am - 9:30am	LESSON'S LEARNED FROM ACHRE; THE EVOLVING SYSTEM OF HUMAN RESEARCH PROTECTIONS Ruth Faden, Ph.D. Executive Director The Phoebe R. Berman Bioethics Institute and the Philip Franklin Wagley Professor of Biomedical Ethics Johns Hopkins University
9:30am - 12:00pm	UPDATE AND DISCUSSION: SOCIAL SCIENCE Felice Levine, Ph.D. Co-chair Working Group, Executive Officer American Sociological Association Jeffrey Cohen, Ph.D. Co-chair, Working Group Director, Education, OHRP/DHHS
[10:30am - 10:45am]	BREAK
12:00pm - 1:00pm	LUNCH

1:00pm - 3:00pm UPDATE AND DISCUSSION: THIRD PARTIES: RESEARCH SUBJECTS?
 Mary Kay Pelias, J.D., Ph.D.
 Chair, Working Group
 Professor of Genetics, Louisiana State University, HSC

[3:00pm - 3:15pm] BREAK

3:15pm - 5:00pm RESEARCH ETHICS OCCASIONED BY THE THE SEPTEMBER 11, 2001
TRAGEDY; CHILDREN & RESEARCH
 Alan Fleischman, M.D.
 Chair, Children's Workgroup
 Senior Vice President, New York Academy of Medicine

5:00pm - 5:15pm WRAP-UP
 Mary Faith Marshall

5:15pm ADJOURN

Wednesday, October 31, 2001

8:30am - 9:00am PROTECTION OF HUMAN SUBJECTS: MANAGING FINANCIAL CONFLICTS
OF INTEREST IN CLINICAL RESEARCH
 Jordan Cohen, M.D.
 President
 American Association of Medical Colleges (AAMC)

9:00am - 9:30am UPDATES: NHRPAC'S FINANCIAL RELATIONSHIPS DOCUMENT;
NHRPAC'S LETTERS TO THE FDA & OHRP RESPECTIVELY ON
EXCEPTIONS FOR CHILDREN'S INFORMED CONSENT AND 45 CFR PART 46
SUBPART B
 Mary Faith Marshall

9:30am - 10:00am BRIEF DISCUSSION ABOUT INDIANAPOLIS CONFERENCE:
ACCOUNTABILITY IN CLINICAL RESEARCH: BALANCING RISK AND
BENEFIT, APRIL 24-26
 Kate-Louise Gottfried, J.D., M.S.P.H.
 Executive Director, NHRPAC

10:00am - 11:30am	<p>Informed Consent--generally Tom Beauchamp, Ph.D. Professor of Philosophy, Georgetown University Senior Research Scholar, Kennedy Institute of Ethics</p>
[10:30am - 10:45am]	BREAK
11:30am - 3:30pm	<p>INFORMED CONSENT AND THE DECISIONALLY IMPAIRED: DISCUSSION OF THE DEPARTMENTS REPORT IN RESPONSE TO NBAC'S REPORT NBAC Report--"Research Involving Persons with Mental Disorders That May Affect Decision Making Capacity" Eric Cassell, M.D. Former NBAC Commissioner Clinical Professor of Public Health Cornell Medical Center</p> <p>HHS Response to NBAC Report Lily Engstrom, M.S. Office of Science Policy, OASPE, DHHS Senior Science Policy Analyst OHRP's Response to HHS's Report Greg Koski, M.D., Ph.D Director, OHRP, DHHS Jonathan Moreno, Ph.D. Director, Center for Biomedical Ethics University of Virginia Health System Adil Shamoo, Ph.D. Professor, Department of Biochemistry and Molecular Biology University of Maryland School of Medicine</p>
12:30pm - 1:30pm	LUNCH
3:30pm - 5:00pm	<p>NHRPAC WORKGROUP MEETINGS</p> <ul style="list-style-type: none"> • Social & Behavioral Sciences • Third parties • Informed Consent & the Decisionally Impaired
5:00pm - 5:30 pm	<p>RECAP OF MEETING & ACTION ITEMS Mary Faith Marshall</p>
5:30pm	ADJOURN

